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# **GMOREGEX User Guide**

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**Abstract**

This document contains the user manual for the GMOREGEX application. It describes in detail the user functionalities provided by the system to the four different types of users for which the system has been implemented, i.e. the generic (non authenticated) user, the Member States National Competent Authorities user, the Commission user and finally a special type of authenticated user that can add comments or observations to GMO notifications based on the authorisation granted by the Competent Authorities and the Commission users.

The GMOREGEX system is a web-based application that enables the electronic support of the GMO notification and authorisation process as defined in Directive 2001/18/EC

[DIR.2001/18]. As specified in the Preparatory Report [PR] and in the Global Implementation Plan [GIP], the system has been developed to support the management of document exchange, information dissemination and events tracking related to the authorisation process for the deliberate release of new GMOs for experimental purposes (Part B notifications and associated SNIFs - [SNIF.PARTB]) or for marketing purposes (Part C releases and associated SNIFs and reports - [SNIF.PARTC]). The processes followed in the system are in accordance to "DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC" and follow the technical specifications and indications contained in the Preparatory Report [PR] and in the Global Implementation Plan [GIP].

This manual is designed to familiarize users with the GMOREGEX system and provide a reference of the system's functionalities and use. The GMOREGEX system includes also the implementation of the GMO Register which supports the storage of information and related documentation of authorised GMOs in the EU, as well as the dissemination of public information to the general public according to the provisions of Art. 31.2 of [DIR.2001/18].

The GMOREGEX system includes also a component that implements the information submission to the Biosafety Clearing House (BCH) in support of the Cartagena Protocol on Biosafety - Regulation (EC) No. 1946/2003 [REG.1946/2003].

The GMOREGEX system supports the following five roles:

- Commission user (COM)
- Competent Authority (CA) user (this role includes both "LEAD CA" and "Non LEAD CA", a CA is given the role of "LEAD CA" for all notifications that are created by users associated to it)
- Authorised External Party (AEP)
- Anonymous user (Guest)

In addition, an administrator role is defined for administration and management of the system:

- System administrator (Admin)

From a functional viewpoint, the GMOREGEX system supports the following high-level functionalities:

- Creation of a new notification (Part B and Part C)
- Management of the lifecycle associated to a new GMO notification (i.e. circulation and publication of information, gathering, sending, collecting and circulation of comments, etc.)
- Dissemination/publication of public information associated to an authorised GMO
- Submission of information to the BCH Central Portal and publication to a EU-based BCH interface
- Reporting
- Advanced search facilities

The current document is partially based on the documentation generated within the project on the implementation of the system carried out with the collaboration of an external contractor.

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